

AMENDMENT TO THE CLAIMS

Applicant respectfully requests that the amendment(s) filed on November 19, 2007, in response to the final Office Action dated September 17, 2007, should not be entered.

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS

1. (previously presented) Stabilized polypeptide particles comprising a polypeptide and a stabilizing agent selected from the group consisting of metal ions and sugars that are stable under acidic conditions at temperatures up to or exceeding physiological conditions, wherein the polypeptide is selected from the pituitary adenylate cyclase polypeptide/glucagon superfamily and the polypeptide particles are formulated to exhibit an acidic reconstitution pH.
2. (original) The polypeptide particles of claim 1, wherein the polypeptide particles comprise a polypeptide, a metal ion and a sugar that is stable at acidic pH at temperatures up to and exceeding physiological conditions.
3. (original) The polypeptide particles of claim 1, wherein the stabilizing agent is selected from disaccharides and monosaccharides that are stable under acidic conditions at temperatures up to and exceeding physiological conditions.
4. (original) The polypeptide particles of claim 3, wherein the stabilizing agent is selected from trehalose and methyl-mannopyranoside.
5. (original) The polypeptide particles of claim 1, wherein the stabilizing agent comprises a stabilizing agent selected from disaccharides and monosaccharides that are stable under acidic conditions at temperatures up to and exceeding physiological conditions and the stabilizing agent is included in the polypeptide particles at a wt/wt ratio of stabilizing agent to polypeptide that ranges between about 0.1/1 to about 1/1.

6. (original) The polypeptide particles of claim 1, wherein the stabilizing agent comprises a stabilizing agent selected from disaccharides and monosaccharides that are stable under acidic conditions at temperatures up to and exceeding physiological conditions and the stabilizing agent is included in the polypeptide particles at a wt/wt ratio of stabilizing agent to polypeptide that ranges between about 0.1/1 to about 0.5/1.

7. (original) The polypeptide particles of claim 1, wherein the stabilizing agent comprises a stabilizing agent selected from disaccharides and monosaccharides that are stable under acidic conditions at temperatures up to and exceeding physiological conditions and the stabilizing agent is included in the polypeptide particles at a wt/wt ratio of stabilizing agent to polypeptide that ranges between about 0.1/1 to about 0.25/1.

8. (original) The polypeptide particles of claim 1, wherein the stabilizing agent comprises a metal ion derived from a divalent metal ion salt.

9. (original) The polypeptide particles of claim 1, wherein the stabilizing agent comprises a metal ion derived from a divalent metal ion salt selected from the group consisting of CaCl_2 , MgCl_2 , and ZnCl_2 .

10. (previously presented) The polypeptide particles of claim 1, wherein the stabilizing agent comprises a metal ion and a molar ratio of the stabilizing agent to the polypeptide included in the polypeptide particles ranges from about 1/1 to about 10/1.

11. (previously presented) The polypeptide particles of claim 1, wherein the stabilizing agent comprises a metal ion and a molar ratio of the stabilizing agent to the polypeptide included in the polypeptide particles ranges from about 2/1 to about 6/1.

12. (previously presented) The polypeptide particles of claim 1, wherein the stabilizing agent comprises a metal ion and a molar ratio of the stabilizing agent to the polypeptide included in the polypeptide particles is about 4/1.

13. (canceled)

14. (previously presented) The polypeptide particles of claim 1, wherein the polypeptide is selected from group consisting of pituitary adenylate cyclase polypeptides, glucagons, glucagon-like particles, growth hormone releasing factor, vasoactive intestinal polypeptide, peptide histidine methionine, secretin, and glucose-dependent insulinotropic polypeptide.

15. (previously presented) Stabilized polypeptide particles comprising pituitary adenylate cyclase polypeptides and a stabilizing sugar selected from trehalose and methyl-mannopyranoside that is stable under acidic conditions at temperatures up to or exceeding physiological conditions, wherein a wt/wt ratio of stabilizing sugar to pituitary adenylate cyclase polypeptide included in the polypeptide particles is about 0.55/1 and the polypeptide particles are formulated to exhibit an acidic reconstitution pH.

16. (previously presented) Stabilized polypeptide particles comprising pituitary adenylate cyclase polypeptides and a stabilizing metal ion selected from Ca^{2+} , Mg^{2+} , and Zn^{2+} that is stable under acidic conditions at temperatures up to or exceeding physiological conditions, wherein a molar ratio of metal ion to pituitary adenylate cyclase polypeptide included in the polypeptide particles is about 4/1 and the polypeptide particles are formulated to exhibit an acidic reconstitution pH.

17-29. (canceled)

30. (currently amended) ~~Stabilized polypeptide particles comprising a polypeptide that is stable under acidic conditions, wherein the polypeptide particles are formulated to exhibit an acidic reconstitution, The stabilized polypeptide of claim 1, wherein the polypeptide is selected from the pituitary adenylate cyclase polypeptide/glucagon superfamily that is stable in near neutral pH environments at temperatures up to and exceeding physiological conditions.~~

31. (original) The stabilized polypeptide particles of claim 30, wherein the stabilized polypeptide particles are formulated to exhibit a reconstitution pH below pH 5.
32. (original) The stabilized polypeptide particles of claim 30, wherein the stabilized polypeptide particles are formulated to exhibit a reconstitution pH between about pH 2 and pH 4.
33. (previously presented) The stabilized polypeptide particles of claim 30, wherein the polypeptide comprises a polypeptide selected from the group consisting of pituitary adenylate cyclase polypeptides, glucagons, glucagon-like particles, growth hormone releasing factor, vasoactive intestinal polypeptide, peptide histidine methionine, secretin, and glucose-dependent insulinotropic polypeptide, and the particles are formulated to exhibit a reconstitution pH below pH 5.
34. (previously presented) The stabilized polypeptide particles of claim 30, wherein the polypeptide comprises a polypeptide selected from the group consisting of pituitary adenylate cyclase polypeptides, glucagons, glucagon-like particles, growth hormone releasing factor, vasoactive intestinal polypeptide, peptide histidine methionine, secretin, and glucose-dependent insulinotropic polypeptide, and the particles are formulated to exhibit a reconstitution pH between about pH 2 and pH 4.
35. (original) The stabilized polypeptide particles of claim 30, wherein the polypeptide comprises a pituitary adenylate cyclase polypeptide analog and the particles are formulated to allow recovery of greater than 90% of the initial pituitary adenylate cyclase polypeptide analog and permit less than 2% dimer formation after two months of storage at 60°C.